diphtheria, catarrh, asthma, bronchitis, fever, headache, earache, toothache, neuralgia, sore throat, pleurisy, pneumonia, diabetes, stomach and kidney trouble, rheumatism, sprains, bruises, cuts, burns, insect bites, poison oak, and similar conditions indicated by the abbreviation "etc.," gravel, and wounds of all kinds; that the article was the most useful all around family remedy known for internal or external uses from the youngest to the oldest; that, when used in conjunction with *Heron's Liver Regulator*, it would be efficacious in the treatment of Bright's disease and diabetes; and that it would be efficacious in the treatment of colds or anything that originates from a cold, whereas the article would not be efficacious for the purposes claimed; and certain statements regarding another drug, *Heron's Constipation Remedy and Liver Regulator*, appearing in an accompanying circular, were false and misleading since they represented and suggested that the other drug was a wonderful relief for the liver, stomach, and bowels, diabetes, and the gall, whereas the other drug was not a wonderful relief for the liver, stomach, or bowels, diabetes, or the gall.

It was also alleged that the defendant had been previously convicted under the Federal Food, Drug, and Cosmetic Act.

DISPOSITION: The defendant subsequently filed a notice of motion to strike from the indictment the allegation of prior conviction and also filed a demurrer to the indictment as a whole for insufficiency and to the prior convinction pleaded therein. On July 10, 1944, the matter came on for hearing, at the conclusion of which the court granted the motion to strike and sustained the demurrer as to all counts of the indictment. On August 9, 1944, the Government filed a petition for an appeal from the district court to the Circuit Court of Appeals for the Ninth Circuit, setting forth that the action in granting the motion to strike the allegation of prior conviction in each count of the indictment and sustaining the demurrer to each count effected a final order setting aside the indictment. On the same date, an order was entered allowing the appeal. On February 20, 1945, following the death of the defendant, an order was entered by the appellate court, abating the action and dismissing the appeal.

1564. Adulteration and misbranding of balsam copaiba. U. S. v. 2 Cans of Balsam Copaiba. Default decree of forfeiture and destruction. (F. D. C. No. 12673. Sample No. 58676–F.)

LIBEL FILED: On or about June 27, 1944, Western District of Virginia.

ALLEGED SHIPMENT: On or about March 13, 1944, by the McCormick Sales Co., from Baltimore, Md.

PRODUCT: 2 cans, each containing 29 pounds, of *balsam copaiba* at Appomattox, Va. The product consisted essentially of a mixture of copaiba, cubeb, alum, and magnesium carbonate.

LABEL, IN PART: (Cans) "29 Lbs. Balsam Copaiba (Mixture) McCormick & Co. Manufacturing Chemists Baltimore, Md., U. S. A."

NATURE OF CHARGE: Adulteration, Section 501 (d), the substances cubeb, alum, and magnesium carbonate had been substituted in part for *balsam copaiba (mixture)*.

Misbranding, Section 502 (a), the label statement, "Balsam Copaiba (Mixture)," was false and misleading as applied to the article, which consisted in part of cubeb, alum, and magnesium carbonate; Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient in the article; and, Section 502 (f) (1), its label failed to bear adequate directions for use.

DISPOSITION: December 4, 1944. No claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1565. Misbranding of Pso-Ridisal. U. S. v. 180 Dozen Packages of Pso-Ridisal (and 6 other seizure actions against Pso-Ridisal). Consent decree of condemnation. Product ordered released under bond. (F. D. C. Nos. 12916, 13398, 13399, 13401, 13595, 13596, 13611. Sample Nos. 59858–F, 63909–F, 66958–F, 66959–F, 68988–F, 86902–F, 87407–F.)

LIBELS FILED: Between the approximate dates of July 27 and October 3, 1944, Northern District of Illinois, Southern District of Florida, Western District of Wisconsin, District of Kansas, and District of Colorado.

ALLEGED SHIPMENT: Between the approximate dates of May 11 and August 9, 1944, by the Sulfa Products Co., from Kansas City, Mo.

PRODUCT: *Pso-Ridisal*, 192 dozen packages at Chicago, Ill., 3 dozen packages at Miami, Fla., 5 dozen packages at LaCrosse, Wis., 21 dozen packages at Wichita, Kans., and 33 packages at Denver, Colo. Analyses of samples disclosed that

the article consisted essentially of sulfanilamide, carbolic acid, mineral oil, a trace of a saponifiable oil, and water.

NATURE OF CHARGE: Portion of article, misbranding, Section 502 (a). Certain statements on the labels of the article and in an accompanying booklet and leaflet entitled "Pso-Ridisal * * * A Sulfa Drug Compound" and "Miracles On the Home Front" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of acne, athlete's foot (ringworm), bed sores, burns, boils, dandruff, eczema, granulated wounds, infective ulcers of the skin, occupational dermatitis, psoriasis, barber's itch, and many other skin irritations, whereas the article would not be an effective medicament in the conditions mentioned. The following statements in the booklet and leaflet: "Is Pso-Ridisal Safe to use? Absolutely. In fact, Pso-Ridisal is so safe it can even be used on a baby's tender skin. In thousands of cases over a period of two and one-half years that Pso-Ridisal has been used, no harmful effects have been reported. * * * There is definite evidence that it is non-toxic as well as non-allergic. * * * Sulfanilamide * * * is absolutely harmless to normal skin tissue"; and "Latest medical reports confirm our findings that reaction from the use of Sulfanilamide are repeatedly negative, while the reaction from at least one of the more popular of the sulfa derivatives is persistently positive. We have found that Pso-Ridisal . . . the new physical form of Sulfanilamide can be used with every assurance of safety as an external treatment. Thousands of reports and many clinical tests give convincing confirmation of this fact" were false and misleading since the article was not safe, but was capable of producing untoward effects and of so sensitizing the user that subsequent administration of a sulfonamide might result in untoward reactions and, further, such sensitization might prevent the use of a sulfonamide in serious disease conditions. The legend "A Sulfa Drug Compound" and the statement "Pso-Ridisal, The New Physical Form of Sulfanilamide," appearing in the labeling of the article were false and misleading since they created the impression that sulfanilamide was the only pharmacologically active component of the preparation, whereas the preparation also contained carbolic acid, a saponifiable oil, and a mineral oil, which are pharmacologically active. The label statement, "Contains Phenol * * * and other inert ingredients," was false and misleading since phenol (carbolic acid) was not an inert ingredient.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual names of the active ingredients, carbolic acid, mineral oil, and a saponifiable oil; Section 502 (f) (1), the labeling of the article failed to bear adequate directions since the directions appearing in the labeling, "Impetigo: Wash affected area with warm water and mild soap. Dry skin thoroughly. Apply solution and massage gently. Open blebs and drain. Repeat application as often as necessary to lubricate skin [or "Keep skin lubricated"]," and "Washing and bathing should be restricted to normal requirements of cleanliness and comfort," did not constitute adequate directions for the use of the article in the treatment of impetigo; and, Section 502 (f) (2), the labeling failed to warn that the use of the article should be discontinued if the skin condition under treatment became worse, if a new rash appeared, or if the patient developed a fever or any other indication of illness, and it also failed to warn that the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions.

Remainder of article, misbranding, Section 502 (a). The legend "A Sulfa Drug Compound" and the designation "Pso-Ridisal," appearing in the labeling of the article, were false and misleading since they implied that the article would be effective for ridding the user of psoriasis, by reason of its content of sulfanilamide, whereas it would not be so effective. Certain statements appearing on the labels of the article and in accompanying booklets and leaflets entitled "Pso-Ridisal * * * A Sulfa Drug Compound," "A First in the Field of Proprietary Medicine," "Miracles On the Home Front," and "Good News for Skin Sufferers" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of acne, athlete's foot (ringworm), bed sores, cuts, burns, boils, dandruff, eczema, granulated wounds, infective ulcers of the skin, dermatitis, psoriasis, and many other skin irritations, whereas the article would not be efficacious for those purposes. The label statement on some packages, "Warning Initial application should be confined to a small area of body to permit comparison between treated and untreated parts. Should undesirable

reaction occur, discontinue use immediately and consult your physician. Use only as directed," created the misleading impression that the only potentially harmful effect the article might have was the causing of a visible or otherwise recognizable reaction on the small area of the body treated, and the statement was also misleading because it failed to reveal the fact, material in the light of the representation, that use of the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions, and that such sensitization might not be recognized by the user. The legend "A Sulfa Drug Compound," appearing in the labeling of the article, was misleading since it created the impression that sulfanilamide was the only pharmacologically active component of the preparation, whereas the preparation also contained carbolic acid and mineral oil, which are pharmacologically active.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient, carbolic acid; Section 502 (f) (1), the following label statements on some packages did not constitute adequate directions for the use of the article in the treatment of impetigo: "Directions This preparation is intended * * * to soothe * * * irritation and discomfort resulting from such skin diseases as * * * Impetigo * * * Shake well before using and then apply locally by a gentle finger massaging of affected parts," and "Impetigo: Wash affected area with warm water and mild soap. Dry skin thoroughly. Apply solution and massage gently. Open blebs and drain. Repeat application as often as necessary to keep the skin lubricated"; and, Section 502 (f) (2), the labeling of the article failed to warn that its use should be discontinued if the skin condition under treatment became worse, if a new rash appeared, or if the patient developed a fever or any other indication of illness, and it also failed to warn that the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions.

DISPOSITION: May 28, 1945. The Nu-Basic Product Co., Royal Oak, Mich., claimant, having admitted the facts of the libels, and the cases having been consolidated for trial in the Northern District of Illinois, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1566. Misbranding of Pso-Ridisal. U. S. v. 1,233 Dozen Bottles of Pso-Ridisal (and 2 other seizure actions against Pso-Ridisal). Consent decree of condemnation. Product ordered released under bond. (F. D. C. Nos. 13314, 13415, 13627. Sample Nos. 81350–F, 81385–F, 81399–F.)

LIBELS FILED: Between the approximate dates of August 11 and September 11, 1944, Western District of Missouri; amended libels filed on or about September 12, 1944.

ALLEGED SHIPMENT: Between the approximate dates of April 19 and August 29, 1944, by the Nu-Basic Product Co., from Royal Oak, Mich.

PRODUCT: 1,302½ dozen bottles of *Pso-Ridisal* at Kansas City, Mo. Analyses of samples disclosed that the product consisted essentially of sulfanilamide, carbolic acid, mineral oil, and water.

NATURE OF CHARGE: Misbranding, Section 502 (a). The legend "A Sulfa Drug Compound" and the designation "Pso-Ridisal," appearing on the label of the article, were false and misleading since they implied that the article would be effective for ridding the user of psoriasis, by reason of its content of sulfanilamide, whereas it would not be so effective. The label statement, "This preparation is intended * * * to soothe the * * * irritation and discomfort resulting from such skin diseases as Psoriasis, Dermatitis, Eczema, * * * Athlete's Foot and Dandruff, and to assist in removing * * * unsightly lesions, was false and misleading because the article would not be effective to soothe the irritation and discomfort resulting from psoriasis, dermatitis, eczema, athlete's foot, and dandruff, or to assist in removing unsightly lesions. The label statement, "Warning Initial application should be confined to a small area of the body to permit comparison between treated and untreated parts. Should undesirable reaction occur, discontinue use immediately and consult your physician. Use only as directed," created the misleading impression that the only potentially harmful effect the article might have was the causing of a visible or otherwise recognizable reaction on the small area of the body treated, and it failed to reveal the fact, material in the light of such representation, that use of the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease